REMARKS

I. Status of the claims

Prior to the above amendment, claims 1-37 were pending. Without prejudice or disclaimer, claims 1-37 have been cancelled and new claims 38-71 have been added. Following entry of this amendment, claims 38-71 will be pending.

Support for claims 38-71 may be found in the as-filed specification and claims, for example, on pages 21-25 and pages 50-55 of the as-filed specification, as well as in Example 1. Accordingly, Applicants submit that the above amendments raise no issue of new matter.

II. Summary of the Requirement for Restriction and Election of Species

In a Requirement for Restriction and Election of Species dated April 14, 2008 (the "Requirement"), the Office requires restriction under 35 U.S.C. § 121 and 372 to one of the following groups of claims for examination:

Group I: Claims 1-31 and 33 are "drawn to a quinazoline derivative of the formula I and a pharmaceutical composition thereof."

Group II: Claim 32 is "drawn to a process for preparing a quinazoline derivative... which comprises either processes a-m."

Group III: Claims 34-36 are "drawn to a method for producing an anti-proliferative effect in a warm-blooded animal... which comprises administering... a quinazoline derivative of the formula I... and uses as a medicament and in the manufacture of a medicament."

Group IV: Claim 37 is "drawn to a compound of the formula VI, VII, VIII, X, or XX, as defined in claim 32, or a salt thereof."

See Requirement, page 2.

As the basis for the Requirement, the Office indicates that Groups I to IV "do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: a) prior art recited in claim 1 of WO 03/082290, provided in the file, anticipates one of the currently claimed quinazoline derivatives of the Formula I." *Id* at pp. 3-4. Furthermore, the Office contends that the application "contains claims directed to more than one species of the generic invention," and that "these species are deemed to lack unity of invention because they are not so linked as to form a single inventive concept under PCT Rule 13.1." *Id.* at 3.

III. Response to the Requirement

In view of the above amendments, Applicants respectfully submit that the Requirement is moot as it currently pertains to cancelled claims. However, Applicants note that new claims 38-40 are respectively directed toward a species of Formula I and a pharmaceutically acceptable salt of that species. Likewise, claims 41-43 are respectively directed toward a pharmaceutical composition comprising that species or a pharmaceutically acceptable salt of that species. The species and salts and compositions thereof were generically grouped within original Group I, as defined by the Office. Thus, it is submitted that new claims 38-43 fall within the scope of original

Group I. Similarly, new claims 44-71, which are directed towards methods for the use of the species and salts are within the scope of original Group III.

In as much as the Office may apply a similar restriction requirement to new claims 38-71, Applicants respectfully traverse such a requirement for the reasons set forth below. However, in an attempt to respond as fully as possible, Applicants elect, with traverse, the subject matter of new claims 38-43, which subject matter is believed to fall within the scope of that originally grouped in Group I, for prosecution on the merits.

Applicants respectfully submit that the originally issued requirement for restriction does not comply with the regulations regarding unity of invention practice for the presently pending claims. Under 37 C.F.R. § 1.475(a), "[a]n international and a national stage application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept ("requirement of unity of invention"). Where a group of inventions is claimed in an application, the requirement of unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art." (emphasis added)

As such, proper consideration of the present claim language in view of PCT rules 13.1 and 13.2 reveals that the pending claims possess unity of invention, and thus shall be examined together. Indeed, claims 38 to 71 contain the same corresponding special technical feature, i.e., the novel species "4-(3-chloro-2-fluoroanilino)-7-methoxy-6-{[1-

(N-methylcarbamoylmethyl)piperidin-4-yl]-oxy}quinazoline, or a pharmaceutically acceptable salt thereof," so as to form a general inventive concept that represents a contribution over the prior art. *See* Claims 38 to 71.

In the present Requirement, however, the Office does not identify a special technical feature incorporated in each of groups I, II, III, and IV, as required by M.P.E.P. § 1893.03(d). Rather, the Office alleges that each of groups I to IV are anticipated by WO 03/082290 ("Himmelsbach") and therefore do not share a common special technical feature.

As clearly set forth in the M.P.E.P. "a claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." M.P.E.P. § 2131 (8th ed. Sept. 2007 Rev.) (quoting *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987)) (emphasis added). To anticipate the claims, Himmelsbach must teach each and every element of the claims.

In the present case, the cited reference fails to meet those requirements. Himmelsbach discloses only very broadly quinazoline derivatives having 3-chloro-2-fluoroanilino moieties tethered to a quinazoline core. There is no example of such substitutions in Himmelsbach, let alone an example of 4-(3-chloro-2-fluoroanilino)-7-methoxy-6-{[1-(N-methylcarbamoylmethyl)piperidin-4-yl]-oxy}quinazoline or a pharmaceutically acceptable salt thereof, as recited in claims 38-71. Rather, a great many examples have a 3-chloro-4-fluoroanilino moiety.

Therefore, Himmelsbach does not disclose each and every element of the present claims 38-71, and consequently does not anticipate the present claims.

Accordingly, any similar restriction requirement that may be applied by the Office to the present claims should be withdrawn for this reason alone.

Further, Applicants respectfully refer the Office to M.P.E.P. § 803, which sets forth criteria and guidelines for the Office to follow in making proper requirements for restriction. There, guidance can be found in the instructions provided to the Office, which guidance is as follows:

> If the search and examination of an entire application can be made **without serious burden**, the Office **must** examine it on the merits, even though it includes claims to independent or distinct inventions.

M.P.E.P. § 803 (emphasis added).

Here, the Office has not shown that examining originally identified Groups I-IV together would constitute a serious burden. In view of the above amendments, Applicant's respectfully submit that the search of the claimed subject matter falling within Group I will substantially, if not completely, overlap with the search for the claimed subject matter falling within Group III as a search of the compound/salt of Group I would necessarily provide a search for the methods of using such compounds. In addition, any burden originally perceived by the Office has been significantly reduced on the Office in that the new compound and method claims have been reduced to a single species. Accordingly, Applicants respectfully request that any requirement for restriction contemplated to be made on new claims 39-71 not be made, or should it be made, be withdrawn, and that present claims 38-71 be examined on the merits.

IV. Rejoinder

If the Office chooses, however, to issue or maintain any of the above mentioned restrictions, in keeping with the provisions of M.P.E.P. § 821.04, Applicants respectfully request that should compound/salt claims 38-43 be allowed, method claims 44 through 71 that depend or otherwise include all the limitations of the patentable product claim be entered as a matter of right and that the rejoined method claims be fully examined for patentability under 37 C.F.R. §1.104

V. Conclusion

In view of the foregoing amendments and remarks, Applicants respectfully request reconsideration of this application and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to Deposit Account 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.

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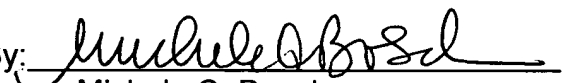
By: 
Michele C. Bosch
Reg. No. 40,524
(202) 408-4193